REMARKS

Claims 8-16, 28, 31, 33, 34 and 36 are currently pending in the application. Claims 8, 9, 10, 16, 28 and 36 are amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

Claim 36 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 36 is also rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. The Examiner states that:

> "In the instant case, a nucleic acid probe 'of 10 to 50 nucleotides in length' is considered new matter. Applicants have not specifically pointed to the portion of the specification for support of this amendment. Upon review of the specification literal support for this amendment can not be found. Support for a probe which is preferably 5 to 150 nucleotides is found on page 15, second to last paragraph. On page 16, last full paragraph support for a fragment that is 'between 15 and 50 bases in length' is found. Additionally, the literal support in the specification is not specifically associated with a probe to detect mutations or polymorphisms which predispose an individual to obesity, rather it is only associated with sequences which are related to fragments which encode a polypeptide. The only size fragment literally supported by the specification is 'about 20 bases in length" for use in PCR reactions (page 16, last paragraph)."

Applicants respectfully disagree. Applicants submit that literal support for a probe of between 10 and 50 nucleotides can be found within page 17, last paragraph of the specification:

> "As used herein, a **probe is e.g. a single-stranded DNA or RNA that has a sequence of nucleotides that includes between 10 and 50,** preferably between 15 and 30 and most preferably at least about 20 contiguous bases that are the same as (or the complement of) an equivalent or greater number of contiguous bases set forth in SEQ ID Nos. 1, 3 and/or 5."

Furthermore, as previously acknowledged by the Examiner, support for between 15 and 50 bases in length is also found within the specification. Applicants further submit that additional support for a probe is found within the same paragraph:

> "Advantageously, it is about 25 bases in length, preferably about 20 bases in length. For differentiating between mutant and wild type 5'OT-EST by PCR reactions, 20mers are the preferred size, whilst for use as probes in, for example, Southern hybridisation, the use of 40mers is preferred."

Other support for probes between 10 and 50 bases in length can also be found within the specification. Described probes, SEQ ID NO:18 – SEQ ID NO:29, vary in length from 18 bp to 25bp. Other aspects of the probe are also disclosed, such as an alignment among 5'OT-EST from human, rat and mouse (Figure 6), how to synthesize nucleic acids (page 17, third paragraph) and its analogs (page 19, paragraph five – page 20, paragraph 2), hybridization conditions (page 16, paragraph 1 – paragraph 5), labeling of the probe (page 18, second paragraph), detecting hybridization (page 18, last paragraph). In light of the extensive support within the specification on probes, Applicants submit that claim 36 is enabled. In light of the foregoing, Applicants respectfully request withdrawal of the §112, first paragraph rejection and reconsideration of the claim 36.

Claims 8-16, 28, 31, 33 and 34 stand rejected and newly added claim 36 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. The Office Action states:

> "The basis of the instant rejection focuses on the breadth of the sequences encompassed by the claims. More specifically, the claims encompass (as set forth in clause (b)) any sequence that will hybridize to SEQ ID NOs: 1, 3, 5, or 7 as it is related to structure and of that structural limitation only the sequences associated with obesity in an animal as it is related to function. The issue is the failure of the specification to describe adequately of which sequences are identified that hybridize, which will meet the functionally [sic] limitations required by the claims."

"In the instant case, the specification is silent with respect to any critical characteristic of a sequence which would be considered a 5'OT-EST. Further, beyond the specific SEQ ID NOs defined to be a 5'OT-EST sequence, the specification is silent with respect to what would be considered a mutation or polymorphism of these specific sequences. Moreover, the specification fails to provide a clear nexus between the SEQ ID NOs and there [sic] consequence on any assayable phenotype of a cell or transgenic animal wherein the artisan could even test any variation of the SEQ ID NO. Again, it is not disputed that the full length cDNA sequences identified in mouse, human and rat are associated with obesity, however, the breadth of the claims is very large encompassing any sort of variant including mutants, truncations, entire gene sequences and any polymorphic sequence that would hybridize under a given set of conditions. The specification does not disclose all these possible embodiments, and even if the structural limitation could be adequately defined by hybridization (see rejection under 35 U.S.C. 112, second paragraph), importantly among all these embodied sequences there is no guidance to which would meet the functional limitations of the claims. The specification is silent with respect to any mutation or polymorphism which is associated with obesity. For example, claims 33 and 34 recite a specific short sequences however these sequences alone are not capable of modulating obesity, even though they may meet the functional requirements of the claims. More simply put given any linear polynucleotide or amino acid sequence the specification fails to provide the necessary guidance to determine whether that particular sequence is functional, and given the uncertainty of the hybridization conditions whether it even meets the structural limitations as well."

"In the instant case, the specification is silent with respect to any critical characteristic of a sequence which would be considered a 5'OT-EST. Further, beyond the specific SEQ ID NOs defined to be a 5'OT-EST sequence from three different species of mammal, the specification is silent with respect to what would be considered a mutation or a polymorphism of these specific sequences. Finally, the specification fails to provide a clear nexus between the SEQ ID NOs and there[sic] consequence on any assayable phenotype of a cell or transgenic animal wherein the artisan could even test any variation of the SEQ ID NO."

"In the instant case, the specification fails to provide any specific or identifying features of a 5'OT-EST beyond the specific sequences set forth as SEQ ID NOs. Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Since the specification is silent with respect to any relevant identifying characteristic of a 5'OT-EST (neither for the polynucleotide nor the polypeptide sequences) the specification fails to provide any nexus between structure and function of a 5'OT-EST which the artisan could use to determine if a sequence with any given structural limitation would be considered a 5'OT-EST."

> "Possession may be shown by clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Because the specification fails to provide any identifying characteristics of the 5'OT-EST sequence it fails to provide an adequate description demonstrating that Applicants were in possession of the invention as broadly claimed. Therefore, for the reasons above and of record, the rejection is maintained."

Without acquiescing to the Examiners statement, Applicants have amended claims 8-10 and 16 so that they no longer claim sequences that hybridize under stringent hybridization conditions to the sequences provided with SEQ ID NOs. For example, claim 8 recites:

> 8. A nucleic acid encoding a 5'OT-EST polypeptide comprising an amino acid sequence selected from the group consisting of the sequences set forth in any one of SEQ ID Nos. 2, 4, or 6.

Furthermore, Claim 28 has been amended to remove clause (b):

> 28. A diagnostic reagent comprising at least one detectably labeled nucleic acid probe of 5 to 150 nucleotides which hybridizes under stringent hybridization conditions in 1M Na^+ at 65°C to a sequence selected from the group consisting of any one of SEQ ID NOs 1, 3 or 5.

Applicants have amended claims 8-10, 16 and 28 solely to expedite prosecution of the instant application. As currently amended, Applicants submit that the specification provides sufficient written description to support claims 8-16, 28, 31, 33 and 34, and therefore respectfully request withdrawal of the §112, first paragraph rejection and reconsideration of the claims.

Claims 8-16, 28, 31, 33, 34 and 36 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action states:

> "claims 8-10, 16 and 28 have been amended to recite nucleic acid sequences "that hybridize under stringent hybridization conditions". The specification provides only a reference to conditions considered to be stringent (page 16, fifth paragraph). The metes and bounds of the claims are indefinite because conditions considered stringent are not clearly set forth. As taught by the specification multiple conditions exist, and 'optimal conditions' must be determined empirically, thus what one would consider "stringent"

would vary from one individual to another. Dependent claims merely set forth that the sequences are in a vector or transformed into a cell. Claims 33, 34 and 36 set forth structural limitations of the sequences (specific sequences and specific range of length), however this fails to further define the conditions in which these limitations would be detected or more specifically define the hybridization conditions encompassed by these claims."

With this amendment, Applicants have amended claims 8-10 and 16 so that they no longer recite "sequences that hybridize under stringent hybridization conditions", and therefore traverse this rejection. Applicants have further amended claim 28 to cite specific hybridization conditions: 1M Na^+ at 65°C:

28. A diagnostic reagent comprising at least one detectably labeled nucleic acid probe of 5 to 150 nucleotides **which hybridizes in 1M Na^+ at 65°C** to a sequence selected from the group consisting of any one of SEQ ID NOs 1, 3 or 5. (emphasis added)

Support for hybridization at 1M Na^+ at 65-68°C is found on page 16, paragraph 2. As such, Applicants submit that claims 8, 16 and 28, as well as dependent claims 9-15, 31, 33, 34 and 36 are definite. As such, Applicants respectfully request withdrawal of the §112, second paragraph rejection and reconsideration of the claims.

With this Amendment, Applicants have made an earnest effort to respond to all issues raised in the Office Action of May 24, 2004, and to place all claims presented in condition for allowance. Applicants submit that in view of the preceding remarks, all issues relevant to patentability raised in the Office Action have been addressed. Applicants respectfully request the withdrawal of rejections over the claims of the present invention. If the Examiner believes that a telephone conversation with Applicant's attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Respectfully submitted,

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